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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,706	08/04/2006	James Adkins Froman	US040123US	7335

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EXAMINER	
SO, ELIZABETH K	
ART UNIT	PAPER NUMBER
4138	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,706	FROMAN ET AL.	
	Examiner	Art Unit	
	ELIZABETH SO	4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/04/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show training electrodes 200 in Figure 2; 2nd layer 510 in Figs. 6 and 7; electrode attachment region or opening 506 in Fig. 6; a child's torso in Fig. 7 or represented by layer 510; and 4th layer 514 in Fig. 8 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

2. The drawings are objected to because Figure 4 is incomplete.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: "the second layer 510" (p. 12, line 15) should be corrected to read "the first layer 502"; and "the child's torso" (p. 12, lines 16-17) should be corrected to read "the adult's torso", or the figures should be corrected as objected above.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-7 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 4 recites the limitation "the electrodes" in the last line of the claim. Claim 5 recites the limitation "the training state notification" in lines 1-2 of the claim. Claim 7 recites the limitation "selection of the training mode" in lines 1-2 of the claim. There is insufficient antecedent basis for these limitations in the claims.

7. Claim 13 is claiming that both a human being and a training apparatus are the subject of claim 1, but the subject cannot be both since the specification discloses that the treatment mode (for a human subject) and the training mode (for a training apparatus) cannot operate simultaneously.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matos (US 2003/0233129 A1) in view of Snyder et al (US 2003/0199929 A1).

Referring to claim 1, Matos shows **an external defibrillator selectably usable in one of a therapy mode** (see pars. 0075-0076) **and a training mode, when in the training mode, having a plurality of training state notifications** (see pars. 0073-0074, 0090, 0096-0099)**, and adapted for electrical coupling with an electrode arrangeable on** an electrode pad (see figs. 5A-5G, where electrode pads 204A, 204B, 206, and/or 208 are connected to the portable unit via cable 212A, 213, and/or 216)**, the electrode electrically conductive and configured for placement on a subject** (see par. 0456)**.** Matos further shows **an energy source** (see par. 0063)**; an electrode interface responsive to the electrode** (see lines 9-10 of par. 1087)**; an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface** (see fig. 20, where the shock protocol is based on the electrode pad assessment of fig. 18F)**; a state identifier, identifying, when the electrode is electrically coupled to the electrode interface, a degree of electrical connectivity along an electrical path including the electrode** (see fig. 18F, element 890)**; a controller, operative in the training mode, prior to placement of the electrode on the subject** (see fig. 18E, elements 871 and 876)**, to advance the external defibrillator from a first training state to a second**

training state when the state identifier identifies a predetermined degree of electrical conductivity along the electrical path (see fig. 18F, element 890)**; and a user interface, operative in the training mode to issue a training state notification indicating that the external defibrillator has advanced from the first training state to the second training state** (see fig. 18F, elements 891, 894, and 896). While Matos shows that the electrodes are arrangeable on an electrode pad or needed to be removed from a backing that protects the adhesive (see par. 2508), Matos does not explicitly disclose that the electrodes are arrangeable on a release liner. Snyder teaches that the electrodes for a defibrillation system are **arrangeable on a release liner** (see lines 2, 6-13, and 30-33 of par. 0009). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Matos' electrode assembly to be arrangeable on a release liner as taught by Snyder, where the motivation to modify would have been to improve the means to detect if the electrodes are fit for use prior to attachment, by measuring the impedance through the release layer.

Referring to claim 2, Snyder shows **the predetermined degree of electrical conductivity comprises an impedance level** (see lines 21-27 of par. 0035).

Referring to claims 3 and 4, Snyder shows that charging the defibrillator occurs at the same time the **electrodes are being removed from the release liner** (see lines 6-13 of par. 0038). The electrodes are determined to be fit for use based on measuring the impedance level against a predefined threshold (see lines 24-27 of par. 0035). Since the impedance level of an electrode on a release liner would differ from the impedance level of the same electrode removed from the release liner, a different result during measurement would indicate that electrode was removed from the release liner. Since charging occurs simultaneously with the removal, one

would also be able to tell that the electrodes have been removed from the release liner without looking at the electrodes. Due to electrical conductivity properties, one would also be able to measure a change in impedance if an **electrode were removed from packaging**, since the moisture content would change upon exposure to the environment outside the packaging.

Referring to claim 5, Matos shows that **the training state notification comprises one of a voice message and a visual prompt** (see lines 21-25 of par. 0033).

Referring to claim 6, Matos shows that **the voice message comprises one of a message instructing a user to remove the electrode from the liner and a message instructing a user to place the electrode on** a patient (see fig. 18E, elements 875 and 880). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a training apparatus in place of the patient when training a user in preparation of an actual defibrillation.

Referring to claim 15, Matos shows **a method for training a user to operate an external defibrillator, comprising providing an external defibrillator selectably usable in one of a therapy mode** (see pars. 0075-0076) **and a training mode** (see pars. 0073-0074, 0090, 0096-0099)**, the external defibrillator comprising an energy source** (see par. 0063)**, an electrode interface responsive to the electrode** (see lines 9-10 of par. 1087)**, the electrode arrangeable on** an electrode pad (see figs. 5A-5G, where electrode pads 204A, 204B, 206, and/or 208 are connected to the portable unit via cable 212A, 213, and/or 216) **and configured for placement on a subject** (see par. 0456)**; and an energy delivery system operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface** (see fig. 20, where the shock protocol is based on the electrode pad assessment of fig.

18F). Matos further shows **advancing the external defibrillator from a first training state to a second training state based on a determined degree of electrical conductivity** (see fig. 18F, element 890)**; and issuing a training state notification indicating advancement from the first training state to the second training state** (see fig. 18F, elements 891, 894, and 896). While Matos shows that the electrodes are arrangeable on an electrode pad or needed to be removed from a backing that protects the adhesive (see par. 2508), Matos does not explicitly disclose that the electrodes are arrangeable on a release liner. Snyder teaches that the electrodes for a defibrillation system are **arrangeable on a release liner** (see lines 2, 6-13, and 30-33 of par. 0009). Snyder further teaches that **when the electrode is coupled to an electrode interface,** the interface can **receive an input signal from the electrode prior to placement of the electrode on the subject and use the input signal to identify a degree of electrical connectivity along an electrical path including the electrode** (see lines 21-27 of par. 0035). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Matos' electrode assembly to be arrangeable on a release liner as taught by Snyder, and measured for impedance as also taught by Snyder, where the motivation to modify would have been to improve the means to detect if the electrodes are fit for use prior to attachment, by measuring the impedance through the release layer.

10. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matos (US 2003/0233129 A1) in view of Snyder et al (US 2003/0199929 A1) as applied to claim 1 above, and further in view of Ungs et al (US 5,275,572).

Referring to claim 7, Matos shows that **the selection of the training mode is based on identification of the electrical coupling of the external defibrillator with an electrode** (see

fig. 18F, elements 890, 891, 894, and 896). Matos does not explicitly say that the electrode may be a training electrode. Ungs shows a **training electrode** for use with an external defibrillator (see fig. 1, element 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Matos' electrode to include Ungs' training electrode, where the motivation to include would have been to provide a practice electrode to prevent needless use of non-training electrodes and thereby save resources.

Referring to claim 8, Snyder shows that **the electrode comprises a conductive attachment layer** (see line 11 of par. 0035) **and a conductive metal layer in communication with the conductive attachment layer** (see lines 9-10 of par. 0035)**, the conductive metal layer having a void therein that provides a nonconductive region within the conductive metal layer** (see lines 9-10 of par. 0035; fig. 5(A), elements 22a and 24a). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Snyder's electrode to be Ungs' training electrode, where the motivation for modification would have been to preserve the structure of a non-training electrode while providing the practice electrode of claim 7.

Referring to claim 9, Snyder shows that **the electrical path comprises a path through the conductive attachment layer and the release layer** (see lines 11-24 of par. 0035).

Referring to claim 10, Snyder shows that there is a predefined threshold or range when measuring and comparing the impedance (see lines 24-26 of par. 0035) so there is **an impedance associated with the electrode.** Therefore, one of ordinary skill in the art would be able to identify an electrode based on the measured impedance, where the impedance is known to be

associated with a type of electrode, where the type of electrode may be a specific kind of **training electrode.**

Referring to claim 11, Snyder shows that a plurality of resistors may be arranged in series in connection to the electrode so that the defibrillation shock is impedance-compensated (see lines 18-24 of par, 0009) and testing the impedance level of the electrode (see lines 3-6 of par. 0038). Since there are a series of resistors between the testing device and electrode, the impedance being measured is affected by the resistance path, so it follows that **the impedance level of the training electrode is based on a resistance value of a resister coupled in series with the training electrode.**

Referring to claim 12, Ungs shows that using the training electrode simulates defibrillation (see cols 4-5, lines 59-2), so that **when the training electrode is attached, the external defibrillator is not operable in the therapy mode**, since the therapy mode is simulated.

Referring to claim 13, Snyder shows that the **subject in therapy mode is a human being** (see lines 1-4 of par. 0024). Snyder does not explicitly show a training apparatus. Ungs shows that the **subject in training mode is a training apparatus** (see fig. 4, mannequin 27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the system as shown in claim 1, by Matos and Snyder, with a training apparatus as taught by Ungs, where the motivation to include a training apparatus would have been for practice and preparation before a real need for treatment, so that the operator could have the confidence and composure to execute the defibrillation properly.

Referring to claim 14, Ungs shows that **the training apparatus comprises a layer having an electrode attachment region defining an area sized to receive the electrode** (see fig. 4, where the mannequin 27 is appropriately sized)**; a signal conductor disposed proximate the electrode attachment region, the signal conductor operable to provide communication between the electrode and the external defibrillator when the electrode is disposed on the electrode attachment region** (see fig. 4, elements 31 and 33)**; and a representation of a subject having the electrode attachment region arranged thereon in a manner that defines a preferred placement area of the electrode on the subject** (see fig. 4, mannequin 27)**.** Since there is a signal generator placed inside the mannequin, which Ungs discloses to also be used for CPR (see col. 2, lines 24-29), the mannequin has a thickness and is three-dimensional. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have created a flattened, virtually two-dimensional training apparatus since the technology at the time the invention was made would have provided small enough circuitry, where the motivation to create such a model would be to take up less space to make the training apparatus more portable and easier to store.

11. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matos (US 2003/0233129 A1) in view of Ungs et al (US 5,275,572).

Referring to claim 16, Matos shows **a method for performing defibrillator training comprising the steps of providing an automatic external defibrillator training device** (see par. 0057, where the external defibrillator can be used as an AED)**; providing multiple single electrode pads in electrical communication with said training device** (see fig. 5G)**; sensing an impedance and advancing a trained rescue based on said sensed impedance** (see fig. 18F,

elements 890, 891, 894, and 896). Matos does not show that the electrodes are training electrodes. Ungs shows a training electrode for use with an external defibrillator (see fig. 1, element 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Matos' electrodes to include Ungs' training electrodes to have **a pair of training electrodes**, where the motivation to include would have been to provide a practice electrode to prevent needless use of non-training electrodes and thereby save resources.

Referring to claim 17, Ungs shows that using the training electrode creates an accurate simulation environment as a training mode (see cols. 4-5, lines 59-2). By using the training electrodes instead of non-training electrodes, one would be **changing an operational mode of said automatic external defibrillator to a training mode based on said sensing step.**

Referring to claim 18, Matos shows **providing a defibrillator training apparatus with depictions of the proper position of each of said training electrodes and wherein said depictions are electrically coupled and connecting said pair of training electrodes to said depictions** (see fig. 18E, elements 874 and 879; and fig. 18F, element 890)**.**

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH SO whose telephone number is 571-270-7405. The examiner can normally be reached on Monday - Friday, 9:30 A.M. - 3:00 P.M., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./
Examiner, Art Unit 4138

/Melba Bumgarner/
Supervisory Patent Examiner
Art Unit 4138